

Patent
Attorney Docket No. 032553-037

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Leigh, Steve et. al.

Application No.: 10/670,504

Filing Date: September 26, 2003

Title: Method and Composition for Solubilising a Biologically Active Compound with Low Water Solubility

Group Art Unit: 2854

Examiner:

Confirmation No.: 8609

FIRST
INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a FIRST Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- ☒ No additional fee for submission of an IDS is required.
- ☐ The fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge _____ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of _____ is enclosed for the fee due.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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Date: April 1, 2004

By

Patrick C. Keane
Patrick C. Keane

Registration No. 32,858



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inter Patent Application of)

Leigh, Steve et. al.)

Application No.: 10/670,504)

Filed: September 26, 2003)

For: Method and Composition for Solubilising)
a Biologically Active Compound with)
Low Water Solubility)

Group Art Unit: 2854

Examiner:

Confirmation No.: 8609

FIRST INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98.

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed. However, copies of the listed U.S. patents and U.S. patent application publications are not enclosed since it is no longer required according to the July 11, 2003 waiver of the requirement for copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003 and international applications entering the national stage under 35 U.S.C. § 371 after June 30, 2003.

The documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required.

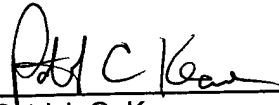
The relevance of these documents is their citation in the specification and/or their citation in a PCT International Search Report, received in connection with what is believed to be a foreign counterpart application to the present application. A copy of the PCT Search Report dated February 5, 2003 is also enclosed.

To assist the Examiner, the document is / documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

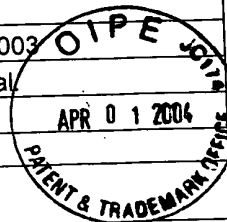
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/670,504	
			Filing Date	September 26, 2003	
			First Named Inventor	Leigh, Steve et. al	
			Examiner Name		
Sheet	1	of	1	Attorney Docket Number	032553-037



U.S. PATENT DOCUMENTS				
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	5,091,188		Haynes	Feb. 25, 1992
	5,747,066		Pittrof et al	May 5, 1998
	4,158,707		Steffen et al	June 19, 1979
	5,192,549		Barenolz et al	March 9, 1993
	5,316,771		Barenholz et al	May 31, 1994
	5,380,531		Chakrabarti et al	Jan. 10, 1995
	5,616,341		Mayer et al	April 1, 1997

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation	
					Yes	No
	WO88/06442		WIPO	Sept. 7, 1988		
	WO00/16770		WIPO	March 30, 2000		X
	WO98/58629		WIPO	Dec. 30, 1998		
	WO86/05694		WIPO	Oct. 9, 1986		
	WO99/49846		WIPO	Oct. 7, 1999		
	WO99/65469		WIPO	Dec. 23, 1999		
	WO97/25977		WIPO	July 24, 1997		
	0 331 755	A1	EPO	Sept. 13, 1989		
	0 974 364	A1	EPO	May 7, 1998		
	0 795 585	A1	EPO	March 7, 1997		
	0 256 090	B1	EPO	July 1, 1992		
	0 158 441	B1	EPO	May 6, 1992		

NON-PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Isele, U.; Van Hoogevest, P.; Hilfiker, R.; Capraro, H-G.; Schieweck, K. and Leuenberger, H., Large-Scale Production of Liposomes Containing Monomeric Zinc Phthalocyanine by Controlled Dilution of Organic Solvents, J. Pharm. Sci. (1994), 83, 1608-1616
	Gopi K. Vudathala and James A. Rogers, Dissolution Of Fludrocortisone From Phospholipid Coprecipitates, J. Pharm. Sci. 81, 283-286 (1992).

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.